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(54) **Atrio-ventricular cardiac pacing catheter**

(57) A catheter assembly for atrio-ventricular pacing, comprises a catheter having proximal and distal ends, the main catheter 10 having a first lumen 12 with an outlet port 20 at the distal end of the catheter and a second lumen 14 having an outlet port 22 at the distal region of the catheter, the outlet port of the second lumen being disposed proximally of the opening for the first lumen; a ventricular lead 16 slidably receivable within the first lumen and an atrial lead 18 slidably receivable within the second lumen, the dimensions and flexibility of the atrial lead being such as to enable the distal end of the atrial lead to straighten when withdrawn into the first lumen and to return to its curved shape when projected out of the first lumen. In use, the leads are positioned with their distal tips located inwardly of the exit ports and the assembly is advanced up to the entry of the right atrium. The ventricular lead is then advanced into the right ventricle and secured and starts functioning to pace the ventricle. The atrial lead is then advanced and the distal end becomes curve shaped and contacts the atrium roof.

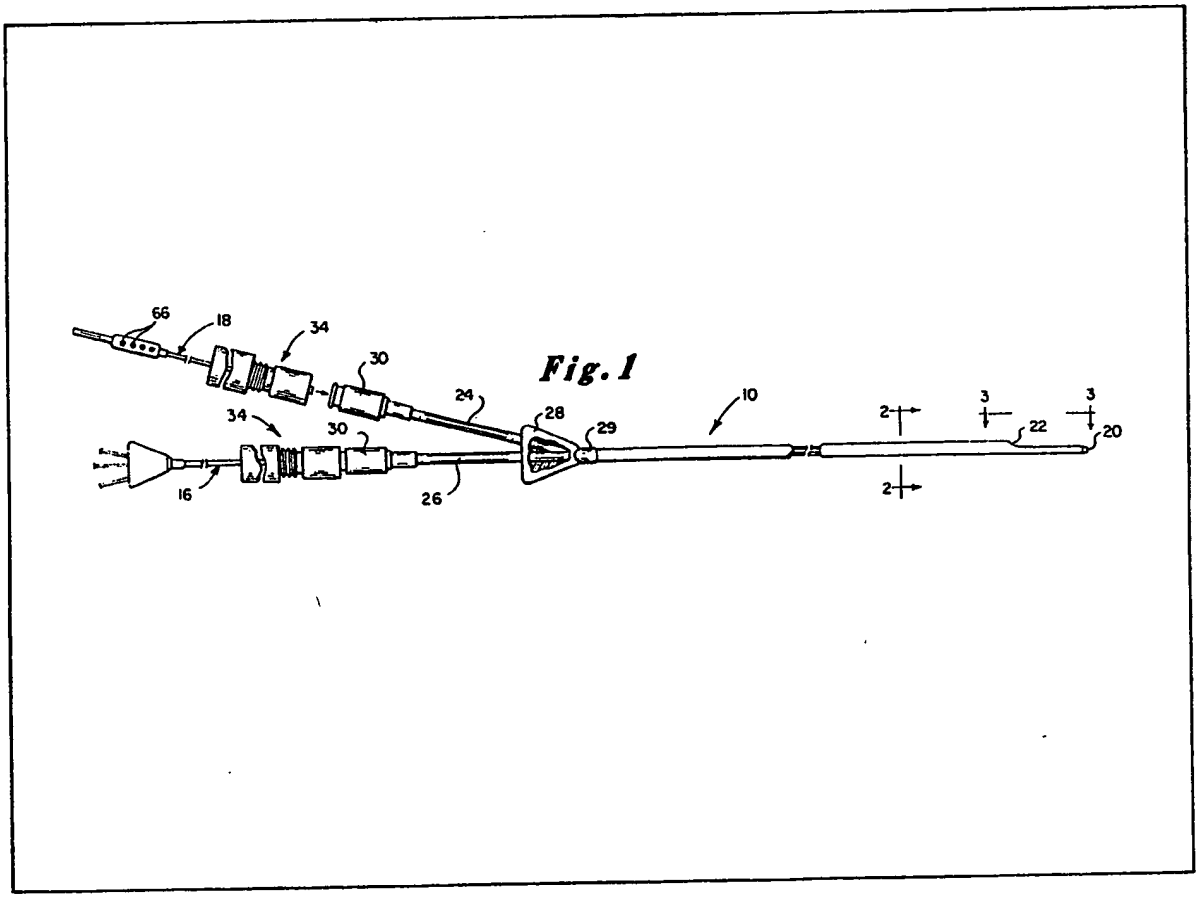

Fig. 1

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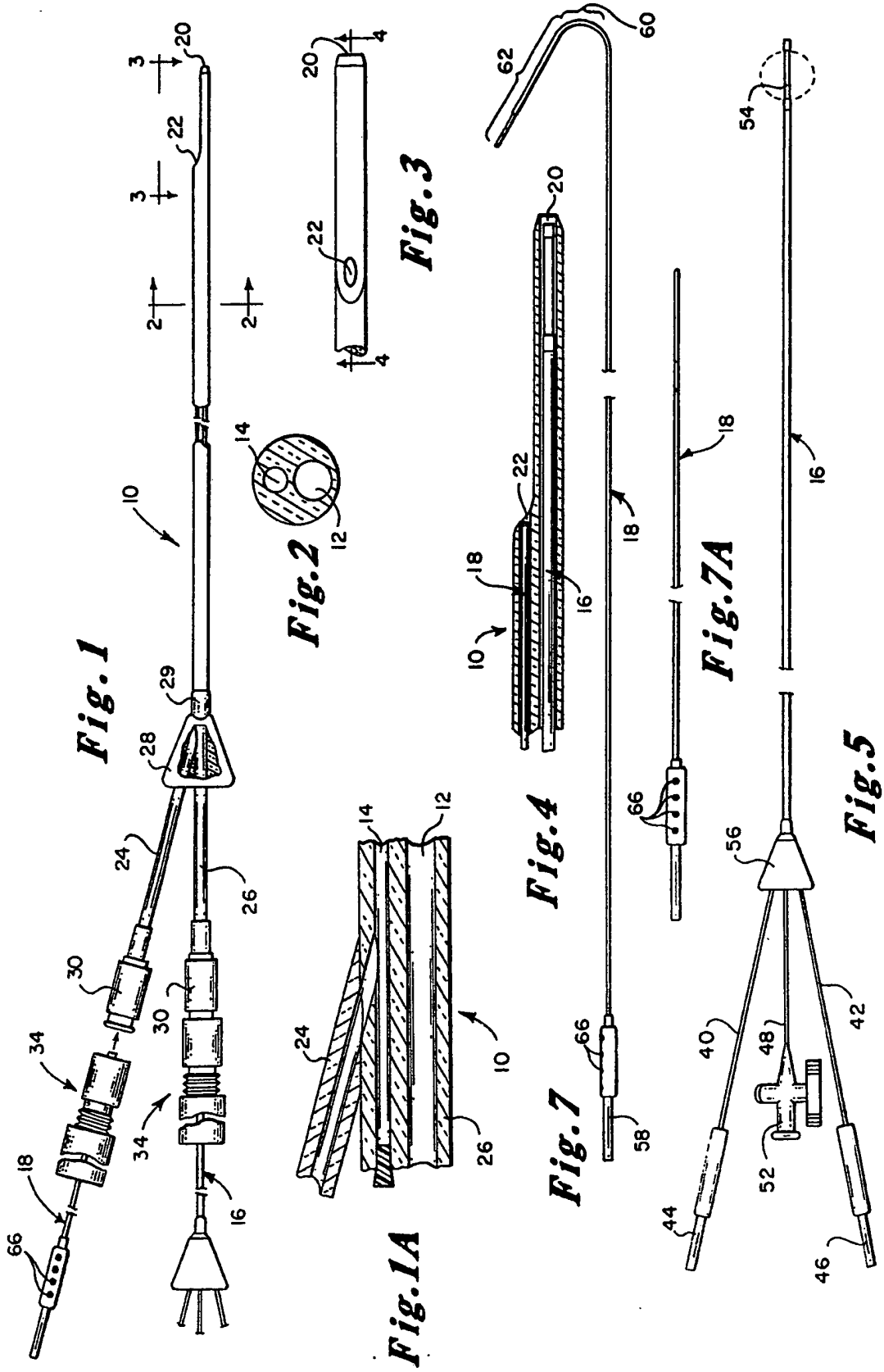


Fig. 1
Fig. 2
Fig. 3
Fig. 1A
Fig. 4
Fig. 7
Fig. 7A
Fig. 5

Fig.6

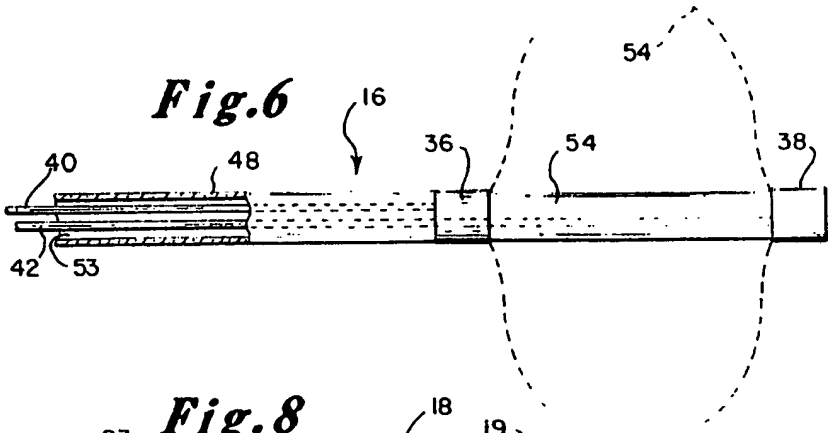


Fig.8

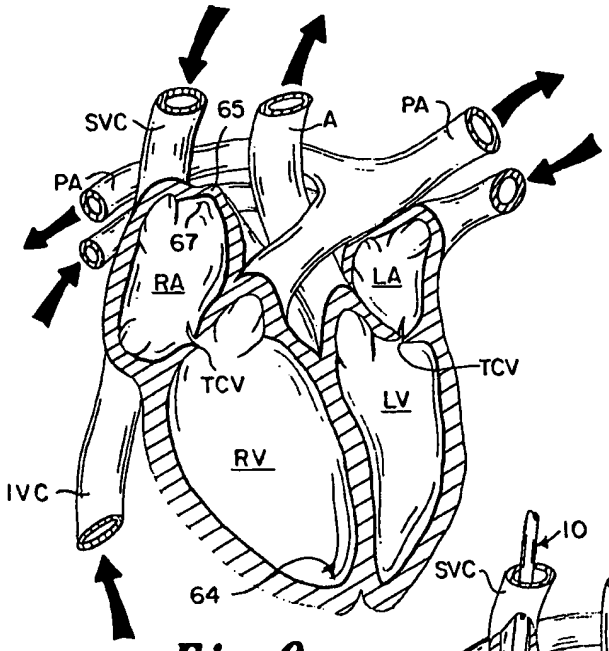


Fig. 9

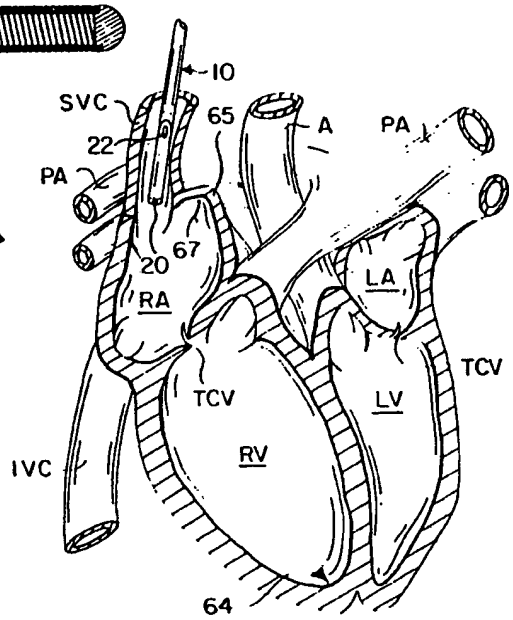


Fig.10

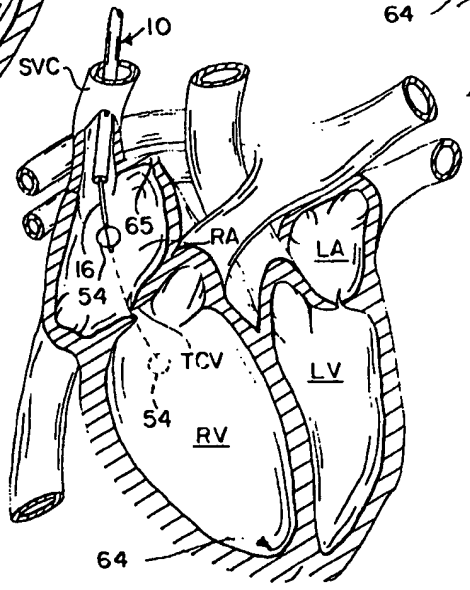


Fig.11

Fig.12

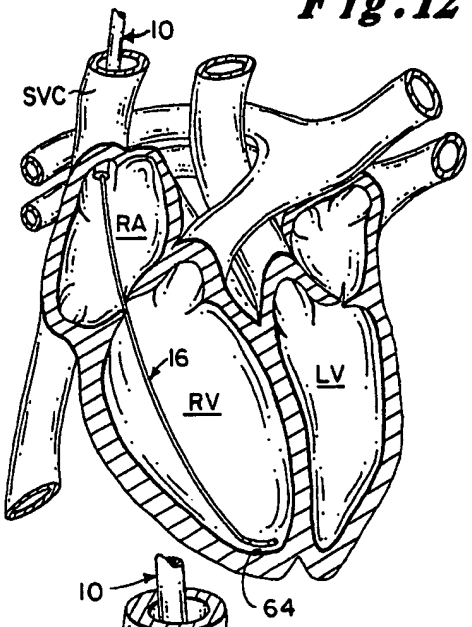
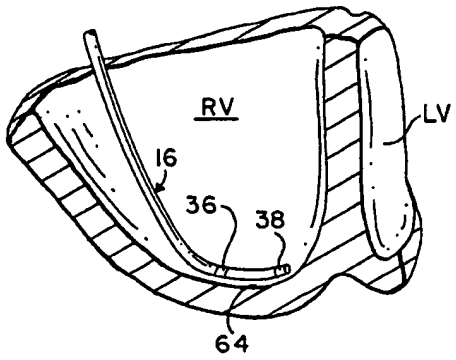


Fig.13



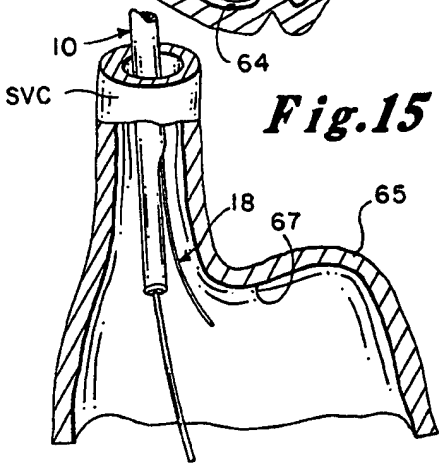


Fig.15

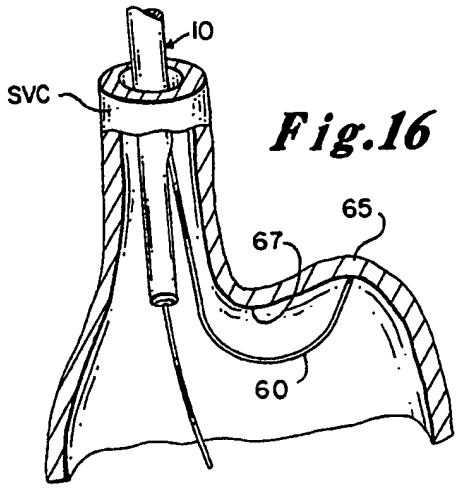


Fig.16

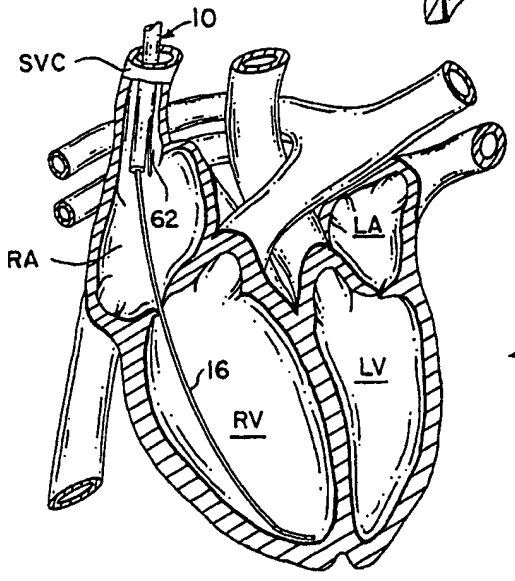


Fig.14

SPECIFICATION

Atrio-ventricular cardiac pacing catheter

The present invention is concerned with cardiac catheters of the type used to control a patient's heart activity by providing electrical pulses to the heart to pace the heart rhythm.

The use of such catheters is often required when there are malfunctions of the heart rhythm. By applying electrical pulses directly to the heart, the rhythmic malfunction may be corrected, at least temporarily, to re-establish more regular heart activity and to stabilise the patient in that condition. Such pacing techniques are used most commonly in emergency situations during post-operative care and in intensive care units for pre-operative as well as post-operative care.

Although a variety of catheters with pacing electrodes are available commercially and are in regular clinical use, they are not free from difficulty. For example, it is often important to establish electrical contact as quickly as possible, such as when trying to restore a functioning heartbeat to a patient under emergency conditions. However, the previously known devices have not lent themselves to a rapid and accurate placement of the electrodes. In some techniques, independent electrodes are placed separately through different veins to contact the atrium and ventricle. Other devices have bundled together a number of electrodes of different lengths which are so arranged that the longer electrodes will reach into the right ventricle, while the shorter electrodes will reach into the right atrium.

Other devices have also been suggested, such as that in U.S. Patent Specification No. 3,949,757, in which atrial and ventricular leads are contained within a sheath and in which the atrial lead is slidable with respect to the sheath so that it may be projected into surface contact with the atrium wall after the ventricular lead has been placed. Although the device described in this U.S. Patent Specification appears to be more convenient to use than the previously known devices, nevertheless it fails to overcome a number of other difficulties. Thus, for example, none of the previously known devices, including that of the above-mentioned U.S. Patent Specification, makes any provision by which the wide variation in heart sizes of various patients may be accommodated. In this regard, it is desirable, for a number of reasons, to place the electrode(s) in direct contact with the heart muscle. Furthermore, it is desirable that certain regions of the ventricle and atrium (for example, the sino-atrial node), which are acutely sensitive to electrical stimulation, be contacted directly by the electrode. However, because of the wide variation, from patient to patient, of the size of the heart, no practical device has hitherto been proposed which was capable of quick and easy placement and adjustment so as to make direct contact with specific portions of the heart muscle, regardless of the size of the patient's heart.

It is desirable, when pacing a heart, to contact the most electrically sensitive areas (such as the sino-atrial node) because that enables lower energy pulses to be used. The use of lower energy pulses is desirable because it tends to create less interference and disruption with other electrically controlled functions of the heart. Until the present invention, precise and reliable placement of the leads in direct contact with selected portions of the heart could not be achieved reliably and, as a result, it was often necessary to apply relatively high energy pulses. The lead was often not in direct contact with the heart wall at all, much less in contact with a particularly sensitive portion of the heart wall. As a result, a higher energy pulse is necessary to overcome the impedance of the blood and the distance between the electrode and the heart wall. In addition, applying a high energy pulse also may interfere with the sensing functions which is often desirable when pacing. Pacemaking equipment often includes sensing circuitry by which the electrical activity and condition of the heart may be monitored by the electrodes in the intervals between pacing pulses. The conditions sensed can be used to control the nature and timing of the pulses applied to the patient. If it is necessary to apply a high energy pulses, as has been common with many of the previously known devices, that tends to disrupt and interfere with the sensing function of the pacemaker.

Another important consideration in cardiac pacing is a proper synchronisation of atrial and ventricular functioning. It is often desirable to pace the atrium and the ventricle in proper sequence so as to achieve as near a normal heart function as possible. This, in turn, may require placement of an electrode in each of the ventricle and the atrium and proper and precise control of the pulsing so that they operate in their normal sequence. In some types of rhythmic disorders, such as heart block, sequential pacing of both the atrium and ventricle is essential.

Still another difficulty present in the previously known devices is the tendency for the electrode leads to become dislodged from their position in the heart as a result of the repeated flexing of the heart in its pumping action. Dislodgement or shifting of an electrode from its intended position disrupts the pulsing and/or sensing functions with potentially serious consequences.

It is an object of the present invention to provide an atrio-ventricular pacing catheter which overcomes the foregoing and other difficulties.

Thus, according to the present invention, there is provided a catheter assembly for atrio-ventricular pacing, comprising

a) a catheter having proximal and distal ends, the main catheter having a first lumen with an outlet port at the distal end of the catheter and a second lumen having an outlet port of the distal region of the catheter, the outlet port of the second lumen being disposed proximally of the opening for the first lumen;

b) a ventricular lead slidably receivable within the first lumen of the catheter, said ventricular lead being longer than said first lumen; and

c) an atrial lead slidably receivable within the second lumen, the atrial lead having a distal end which is shaped so that it will assume a predetermined curve when in a relaxed configuration, the

dimensions and flexibility of the atrial lead being such as to enable the distal end of the atrial lead to straighten when withdrawn into the first lumen and to return to its curved shape when projected out of the first lumen.

In accordance with the present invention, the device is arranged so that the ventricular lead may be advanced into contact with the ventricular apex and the atrial lead may be advanced into contact with the atrial appendage. The ventricular apex and atrial appendage each define somewhat concave surfaces within the heart and provide concave surfaces which tend to provide an increased degree of stability for an electrode which bears against that surface under a light spring-like pressure. The atrial appendage is located in the roof region of the atrium in close proximity to the electrically sensitive sino-atrial node. Because the sino-atrial node, as well as the atrial appendage, are in the roof region of the atrium, they are difficult to reach, it being an object of the present invention to provide an inproved system which facilitates making direct electrical contact with those roof regions of the atrium.

When in use, the leads are positioned in the main catheter with their distal tips located just inwardly of their respective exit ports and the assembly is advanced, in that configuration, through the superior vena cava until the distal end of the catheter is just at the entry to the right atrium, the catheter being secured in that position. The ventricular lead is then advanced through the catheter so that its distal tip passes through the right tricuspid valve of the heart and into the right ventrical. The distal end of the ventricular lead is provided with a balloon which, if the patient has any blood flow, may be inflated during the insertion procedure to help to advance the ventricular lead through the tricuspid valve and into the right ventrical with the blood flow. Once in the right ventricle, the balloon is deflated so that the electrode at the distal tip of the ventricular lead can be urged into a stable position in contact with the ventricular apex. Ventricular pacing may begin immediately upon contact with the electrode(s) at the distal tip of the ventricular lead with the surface of the ventricle.

Once the ventricular lead is secured in place and is functioning to pace the patient's ventricle, the atrial lead may be placed. That is accomplished simply by manipulating the proximal end of the atrial lead to advance the atrial lead and cause the distal end to project out of the atrial lumen. According to the present invention, the outlet for the atrial lumen is located proximally of the outlet for the ventricular lead and the lumen is located offset from the centre of the main catheter. As the atrial lead emerges from its exit port, its distal tip assumes a J-shape and it will be in a better position to reach and contact the roof region of the atrium and the concave surface of the atrial appendage. The device is arranged so that the atrial lead may be controllably manipulated from its proximal end in longitudinal as well as in rotational directions. Thus, the present invention provides a high degree of control in the placement of the atrial lead. The proximal end of the atrial lead is provided with appropriate markings to facilitate positioning. Means (Tuehy-Borst adapters) are provided to secure the leads in their respective positions with respect to the catheter.

The present invention will now be described in more detail, with reference to the accompanying drawings, in which:

Figure 1 is an illustration, partly in section, of the catheter assembly, including the catheter containing the ventricular and atrial leads positioned as they would be when the assembly is introduced to the patient;

Figure 1A is a sectional illustration of the bifurcation of the catheter;

Figure 2 is a cross-section of the catheter assembly as seen along line 2-2 of Figure 1;

Figure 3 is a plan illustration of the distal portion of the catheter as seen along the line 3-3 of Figure 1;

Figure 4 is an enlarged sectional illustration of the distal portion of the catheter as seen along the line 4-4 of Figure 3 and illustrating the positions of the distal ends of the ventricular and atrial leads when the assembly is introduced into the patient;

Figure 5 is an illustration of the ventricular lead showing, by broken lines, a flow assist balloon in its inflated configuration;

Figure 6 is an enlarged illustration of the distal end of the ventricular lead;

Figure 7 is an illustration of the atrial lead;

Figure 7A is an illustration of the proximal and distal ends of the atrial lead, showing the plane of the relaxed curved distal end and its alignment with indicia at the proximal end;

Figure 8 is an enlarged illustration of the distal tip of the atrial lead; and

Figures 9-16 illustrate diagrammatically portions of a patient's heart and the manner in which the present invention is used.

Referring now to Figure 1, the catheter assembly includes a main catheter 10, which may be extruded from an appropriate plastics material, such as a fluoroethylene polymer. The main catheter 10 is formed with a pair of lumens, including a ventricular lead lumen 12 and an atrial lead lumen 14. The ventricular lead lumen 12 is larger in diameter than the atrial lead lumen 14 and is intended to receive the relatively larger diameter ventricular lead 16. The smaller lumen 14 slidably receives the atrial lead, indicated generally at 18. The lumens 12 and 14 are arranged side-by-side with at least the atrial lumen 14 being displaced from the central axis of the main catheter 10.

The ventricular lumen 12 extends fully along the length of the main catheter 10 and terminates in an exit port 20 at the distal tip of the main catheter 10. The atrial lead lumen 14 terminates in an exit port 22 which is spaced proximally from the distal end of the catheter 10. In a preferred embodiment of the present invention, the exist port 22 for the atrial lead 18 is disposed approximately one centimetre proximally of the ventricular lead outlet 20. When the atrial lead 18 is advanced through the lumen 14, it will emerge from exit port 22 before reaching the distal tip of the catheter 10 and, as will be described hereinafter, will assume a J-shaped configuration as it emerges from the exit port 22.

The proximal portion of the main cather 10 is bifurcated to include and define an atrial guide tube 24 and a ventricular guide tube 26. The ventricular guide tube 26 may be defined by a continuation of the main catheter 10 with the atrial lead lumen 14 obstructed. The atrial guide tube 24 may be formed from a separate tube which is spliced to the main catheter 10 so that it communicates only with the atrial lead lumen 14, as indicated in Figure 1A. The spliced region may be encapsulated in a moulded plastics fitting 28. The distal portion 29 of the moulded fitting 28 is preferably formed with a taper so that it may be detachably locked to a corresponding fitting on a catheter introducer, as will be described hereinafter in further detail.

The proximal ends of the atrial and ventricular guide tubes 24 and 26 are preferably provided with standard luer fittings 30. Each of the luer fittings 30 is preferably provided with a lockable, sealing fitting indicated by 34, for example, a Tuehy-Borst fitting. The fittings 34 enable an element, such as the atrial or ventricular lead, to be passed through the fitting and then tightened to lock the leads 16 and 18 in place and effect a seal about the lead, as will be described hereinafter in further detail.

The ventricular lead 16 is shown in more detail in Figures 5 and 6. It is substantially longer than the guide catheter 10 and, for example, may be of the order of 50 cm. in length. The lead 16 may be formed from a slender tube 48 of extruded plastics material with insulated electrical wires 40 and 42 carried in tube 48. As shown in more detail in Figure 6, the ventricular lead 16, in accordance with the present invention, is bipolar, having a pair of spaced ring electrodes 36 and 38 at its distal end. The electrodes 36 and 38 are each electrically connected to insulated wires 40 and 42 which emerge at the proximal end of the lead and terminate in connectors 44 and 46 (see Figure 5). The tube 48 emerges at the proximal end of the ventricular lead and is connected to a stopcock 52. The tube 48 thus also defines an inflation lumen 53 for a balloon 54 which is attached to the distal end of the lead, between the ring electrodes 36 and 38. The ventricular lead is provided with a moulded plastics member 56 at the trifurcated region of the tube 48 and wires 40 and 42. As will be described hereinafter in further detail, the balloon 54 may be inflated to facilitate guidance of the ventricular lead into proper placement and advancement through the tricuspid valve and into engagement with the ventricular apex.

The atrial lead 18 is illustrated in Figures 7 and 8 and may be about 40 cm. in length. The lead 18 is illustrated as being monopolar and formed from a wound spring wire 19 having a central core wire 21 similar to a conventional construction for a spring guide. However, the core wire terminates approximately 8 mm. from the distal tip of the lead so that the distal region will be soft and flexible. The proximal end of the atrial lead includes a connector plug 58 for attachment to a pacemaker. The atrial lead 18 is covered along its length with an insulating jacket 23, which may be formed from a shrinkable plastics material, shrunk on to the spring wound lead. The jacket 23 may be formed, for example, from TFE plastics material and covers all of the lead except for the most distal five millimetres, which serves as the atrial electrode.

As shown in Figure 7 the distal end of the atrial lead 18 is formed so that, when in a relaxed state, it will assume a somewhat J-shaped configuration having a curved segment 60 and a most distal straight segment 62. The curved segment 60 extends through an arc of approximately 150°. The diameter of the atrial lead 18 is approximately 2 French (0.65 mm.) and, therefore, is flexible so that the atrial lead 18 can flex easily to a straight configuration so as to be fully contained and easily slidable within the atrial lead lumen 14 of the main catheter 10.

The manner in which the present invention may be used is described with reference to Figures 9 to 16, which illustrate the human heart and the various positions of the distal portions of the main catheter 10 and of lead 16 and 18. As shown diagrammatically in Figure 9, in a properly functioning heart, blood returns from the venous system through the superior vena cava (identified as SVC in the drawings) and inferior vena cava (IVC) to the right atrium (RA) of the heart. When the right atrium contracts, it pumps blood through the one-way tricuspid valve (TVC) into the right ventricle (RV). The right ventricle (RV) then contracts to close the tricuspid valve (TVC) under pressure and to pump blood through the pulmonary arteries (PA) to the lungs, where the blood is oxygenated. The oxygenated blood then flows through the pulmonary veins to the left atrium (LA), through the left tricuspid valve and then into the left ventricle (LV). The left ventricle pumps blood through the aorta (A) throughout the body and then through the venous system to return the blood to the heart and renew the cycle.

As will be described in further detail, one facet of the present invention relates to the ability of the leads to be placed in concave portions of the atrium and ventricle, which will tend to retain the electrodes in a stable position so that the electrodes will not become dislodged as the heart flexes and pumps repeatedly. To that end, the present invention contemplates engaging the ventricular lead with the ventricular apex at the lowermost portion of the right ventricle, as shown by 64 in Figure 9. The ventricular apex is concave and provides a stable location from which the electrodes at the end of the ventricular lead will not become dislodged from their contact with the heart wall. The ventricular apex 64 is considered a satisfactory location in which to make electrical contact between the ventricular lead, both for pacing and sensing functions.

In accordance with the present invention, the portion of the right atrium which is most desirably contacted with the atrial lead is the atrial appendage 65, a portion of the heart which is located in the roof region of the atrium which defines a concave surface, as would be seen from within the atrium. Although the atrial appendage 65 is not as sensitive electrically as the sino-atrial node (indicated by 67 in Figure 9), it is adjacent to the sino-atrial node and, therefore, is close enough to it to provide substantially low impedance for the pacing and sensing signals to be highly effective. The atrial appendage

65 is a relatively delicate membranous portion of the heart and it is important, therefore, that the atrial lead be so constructed that it will make contact in a very delicate manner.

Normally, the self-regulating electrical activity of the heart causes the right atrium RA and right ventricle RV to contact in sequence, with the right atrium RA contracting first to pump blood through the tricuspid valve TVC and into the right ventricle RV, the right ventricle RV then contracting after a short delay. The delay in the contractions of the right atrium RA and right ventricle RV are sufficient to enable the atrium to pump blood through the tricuspid valve TCV and into the right ventricle RV.

Various disorders can occur with respect to the electrical control of the function of the heart. Typically, when there is a disruption in the normal electrical activity of the heart, it is essential first to re-establish a regular rhythm in the right ventricle so as to maintain at least a sufficient flow of blood to the lungs in order to provide at least a minimally sufficient supply of oxygenated blood to the patient. It is preferred and, in some instances, it is necessary also to establish a proper sequential rhythm for the atrium so as to maximise the pumping efficiency of the heart. Thus, as soon as possible after the ventricular lead has been placed and pacing has begun, it is desirable to place and begin pacing with the atrial lead.

The catheter 10 of the present invention is introduced intravenously, preferably through the internal jugular or subclavian vein, which leads to the superior vena cava SVC. Any of a variety of well-known techniques may be employed, such as inserting a catheter introducer percutaneously to provide access to the vein. The device is arranged so that the leads 16 and 18 are within their respective lumens 12 and 14, with their distal ends located just proximally of their openings 20 and 22 (as indicated in Figure 4), in readiness to be advanced. The assembly, with the leads so positioned, is advanced through the catheter 10 introducer until the distal tip of the catheter is at the region of the juncture between the superior vena cava SVC and the right atrium RA, as illustrated in Figure 10. The procedure is preferably monitored on a fluoroscope, from which the positioning of the various elements can be verified. The assembly should be positioned so that the outlet port 22 of the catheter 10, from which the distal end of the atrial lead will emerge, is sufficiently close to or just within the atrium so as to assure that the atrial lead will advance and extend properly into the upper region of the atrium, as will be described hereinafter. When the catheter 10 is properly positioned, it is secured in place by any appropriate means, such as by taping it firmly to the patient or by securing the tapered portion 29 of fitting 28 to the conventional fitting at the proximal end of the introducer, or by a combination of such means. Once the guide catheter 10 is in place, it will not have to be moved again until it is to be removed.

The ventricular lead 16 is then advanced, the sealing gland 34 first being released to free the ventricular lead for movement. If the balloon is to be inflated, as shown in Figure 11, the ventricular lead 16 is then advanced slightly to project the balloon tip outwardly beyond the distal opening 20. The balloon may be inflated with gaseous carbon dioxide by means of a syringe connected to the stopcock 52. With the balloon inflated, the ventricular lead is advanced through the main catheter 10. The balloon, when used, flows with the blood flow and provides assured guidance that the ventricular lead 16 will flow to and through the tricuspid valve TCV into the right ventricle RV instead of passing downwardly into the inferior vena cava IVC or at some other angle. The balloon may be used with some effectiveness only when the heart has some pumping function and there is some blood flow. When there is no pumping function and no blood flow, the system may be used without inflating the balloon.

Once the distal end of the ventricular lead is in the right ventricle RV (as suggested in outline in Figure 11), the balloon is deflated (if it had been previously inflated) and the distal end of the ventricular lead is advanced into the pocket-like ventricular apex 64. The ventricular lead is advanced to the position shown in Figure 12, in which it is assured that its distal end has been bent so that both ring electrodes 36 and 38 are in contact with the heart muscle in the region of the apex 64, as shown in enlarged detail in Figure 13. Proper electrical contact with the ring electrodes 36 and 38 can be assured by monitoring the electrical pacing device and sensing feedback signals indicative of proper electrical contact. When the surgeon is satisfied that the ventricular lead 16 is properly placed, securely contained within the pocket defined by the ventricular apex and in good direct electrical contact with the heart, the ventricular lead is locked in place by fastening the Tuehy-Borst adapter 34.

In the illustrated embodiment, the preferred electrode configuration for the ventricular lead is bipolar, i.e. there are two ring electrodes 36 and 38 which will electrically contact the surface of the heart muscle at the ventricular apex. By applying a pulse across these two closely spaced electrodes, only that portion of the heart which is in the region of the electrodes is affected by the pulse. Because electrical activity within the heart muscle is very complex, it is desirable to apply pulses only at a location and of an energy level which will be sufficient to pace the heart but without disrupting any other electrical function of the heart. Thus, with the bipolar ventricular lead shown in the illustrated embodiment, electrical energy is applied only to the heart in a small localised region sufficient to pace and to sense the activity of the right ventricle and without affecting other portions of the electrical activity of the heart.

After the ventricular lead 16 has been placed, the atrial lead 18 is placed. The sealing gland 34 associated with the atrial lead is unlocked and the atrial lead 18 is advanced so that its distal end emerges from the outlet port 22. As the atrial lead emerges, the most distal straight segment 62 will emerge, paralleling the catheter 10, as shown in Figure 14. As advancement of the atrial lead continues, the curved segment 60 begins to emerge from the outlet port 22 and the lead begins to assume its J-shape, as shown in Figure 15. Before

the atrial lead expands to its normally relaxed, full J-configuration, the distal tip will engage and drag against the uppermost roof surfaces of the right atrium RA, as shown in Figure 16. Further advancement of the atrial lead will project it more distally out of the exit port 22 and downwardly from the roof of the atrium until is assumes a fully relaxed configuration. The surgeon may then control the position of the atrial lead by manipulating it from its proximal end, both longitudinally and rotationally. By such manipulation, the surgeon can place the electrode at the distal tip at precisely the location on the roof region of the atrium which he desires. This enables the surgeon to place the atrial electrode precisely against the concave atrial appendage. As described above, the atrial appendage defines a somewhat concave socket which provides a stable location for electrode contact. The surgeon can verify that contact has been made with the atrial appendage by monitoring the feedback of electrical signals. When the surgeon is satisfied that the atrial lead is in proper contact, the Tuehy-Borst adapter is tightened down about the atrial lead to secure it in position.

The foregoing description of the atrial lead relates to a monopolar configuration in which the distalmost tip defines a single electrode. A grounding electrode for use with the monopolar electrode may be in the form of an externally applied electrode patch, such as the type commonly used in electrocardiogram procedures. Alternatively, the atrial lead may be formed so as to be bipolar in similar manner to the bipolar configuration of the ventricular lead. Whether monopolar or bipolar, it is important that the distal tip of the atrial lead be flexible and resilient to assure avoidance of trauma to the delicate membranes in the roof region of the atrium.

With the main catheter 10 and both leads 16 and 18 secured in position and particularly when the ventricular and atrial leads are in engagement with the ventricular apex and the atrial appendage, respectively, the concave contacting regions materially reduce the chances of the leads becoming dislodged due to the influence of the pumping action of the heart.

From the foregoing, it will be appreciated that the present invention may be used with all patients, regardless of variations in heart size, because each of the leads is positioned independently with respect to each other and also independently with respect to the catheter.

Means are also provided to facilitate positioning and orientation of the atrial lead by reference to the relative position of the proximal end of the lead, as compared to the catheter 10. For that purpose, the proximal end of the atrial lead is preferably marked with indicia, indicated by 66 in Figure 7A, to indicate the radial plane in which the distal end portions 60 and 62 of the atrial lead project. By comparing the portion of marking 66 with the position of the guide tube 24 or some other indicia indicating the side of the guide catheter 10 where the outlet port 22 is located, the surgeon can determine the relative angular position of the distal end of the atrial lead with respect to the main catheter and, therefore, with respect to the patient's heart. By using such reference points, the surgeon will be able to direct the distal end of the atrial lead into close proximity, if not precise contact, with the atrial appendage quickly and with minimal manipulation.

Also among the features of the present invention is the relative location of the exit port 22 with respect to the distal tip of the catheter 10. When the catheter 10 is positioned so that its distal tip 20 is located just at the juncture of the superior vena cava SVC and the right atrium RA, the exit port 22 for the atrial lead will be located somewhat within the superior vena cava. However, as the atrial lead emerges from the opening 22, it advances substantially along and parallel to the catheter 10 and begins to assume its curl just as the electrode tip of the atrial lead enters into the upper portion of the atrium. Thus, as the atrial lead is advanced, it will begin its curl in close proximity to the roof of the atrium and will contact and brush against the roof of the atrium before it assumes its fully opened J-configuration. If the surgeon has advanced the atrial lead in a rotative position which would cause the atrial electrode to contact the atrial appendage directly, then the atrial lead may be secured in that position immediately. Otherwise, the atrial lead may be advanced further into the atrium to enable the J to expand fully, free of the atrial wall, so that the surgeon can rotate the atrial lead to the desired angular position and then draw the lead proximally to bring it into contact with the atrial appendage.

From the foregoing, it will be appreciated that the present invention provides significant advantages over the prior art and the presently employed systems. The system can be used with equal effectiveness on any patient, regardless of the size of the patient's heart. It enables rapid deployment of the ventricular and atrial leads in sequence. It enables both the ventricular lead and the atrial lead to contact concave regions of the ventricle and atrium respectively and particularly the atrial appendage of the right atrium to assure the mechanically stable positioning of both ventricular and atrial leads so that they will not likely be dislodged as a result of the pumping action of the heart. Furthermore, these advantages are achieved in a pacing/sensing catheter in which the electrodes make direct contact with the endocardium, thereby reducing the amount of power which must be applied to the leads and enabling a more precise control of the pacing and sensing functions.

CLAIMS

1. A catheter assembly for atrio-ventricular pacing, comprising

a) a catheter having proximal and distal ends, the main catheter having a first lumen with an outlet port at the distal end of the catheter and a second lumen having an outlet port at the distal region of the catheter, the outlet port of the second lumen being disposed proximally of the opening for the first lumen;

b) a ventricular lead slidably receivable within the first lumen of the catheter, said ventricular lead being longer than said first lumen; and

c) an atrial lead slidably receivable within the second lumen, the atrial lead having a distal end which is shaped so that it will assure a predetermined curve when in a relaxed configuration, the dimensions and flexibility of the atrial lead being such as to enable the distal end of the atrial lead to straighten when withdrawn into the first lumen and to return to its curved shape when projected out of the first lumen.

2. A catheter assembly according to claim 1, wherein the first lumen is offset from the central axis of the catheter.

3. A catheter assembly according to claim 1 or 2, wherein the proximal end of the catheter is formed to define a bifurcation, said bifurcation including tubular guide means for communication with each of the first and second lumens, sealing and locking means being associated with each of the guide tubes for gripping and locking the lead in selected positions.

4. A catheter assembly according to any of the preceding claims, wherein the curved configuration for the distal tip of the atrial lead comprises a first, arcuate segment extending from the atrial lead and circumscribing an arc of approximately 150°, and a second, straight segment extending from the distal end of said arc segment, the second segment being approximately 15 mm. in length, the most distal portion of said second segment comprising an exposed electrode means.

5. A catheter assembly according to claim 4, wherein the most distal portion of the second segment is more flexible and resilient than the more proximal portions thereof.

6. A catheter assembly according to any of the preceding claims, wherein the ventricular lead further comprises a bipolar electrode having a pair of spaced electrodes at the distal tip.

7. A catheter assembly according to any of the preceding claims, wherein an inflatable balloon is provided at the distal tip for flow assist purposes to guide the lead along the flow path through the tricuspid valve of the heart, and means in communication with the proximal end of the ventricular lead for inflating and deflating the balloon.

8. A catheter assembly according to any of the preceding claims, wherein the outlet port for the second lumen is approximately 1 cm. proximal of the outlet port for the first lumen.

9. A catheter assembly according to any of the preceding claims, wherein a curved configuration for the distal tip of the atrial lead comprises a first arcuate segment at the distal end of the atrial lead and a second, straight segment, extending from the distal end of the arc segment, the second segment having a length no shorter than the distance between the outlet ports of the first and second lumens.

10. A catheter assembly according to any of the preceding claims, wherein the atrial lead is constructed so that its predetermined curve at its distal end lies substantially in a plane and indicia means at the proximal end of the atrial lead correspond to and provide an indication of the rotational orientation of the curve.

11. A catheter assembly according to any of claims 1 to 10, substantially as hereinbefore described and exemplified and with reference to the accompanying drawings.

12. An atrial lead for use in cardiac pacing, comprising an elongate flexible lead having electrode means at its distal end and connector means at its proximal end, the distal end of the lead being formed to define a curved configuration in its relaxed state, said curved configuration including a first arcuate segment circumscribing approximately 150° and a more distal straight segment extending about 15 mm. in length, the electrode means being formed on said distal straight segment; said atrial lead being constructed so that it may be straightened in its entirety, including its distal tip, whereby the lead may be advanced through the catheter; said lead being constructed and arranged so that its emergence of its distal end from the outlet port of a catheter will be in a sequence in which the most distal straight segment projects substantially straight out of the exit port and in which the distal end of the atrial lead does not begin to assume its curved configuration until the curved segment begins to advance out of the exit port.

13. An atrial lead according to claim 12, substantially as hereinbefore described and exemplified and with reference to the accompanying drawings.

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